

## **REMARKS**

In the Office Action dated February 21, 2003, claims 26-42 are pending. Claims 30-36 are under consideration. Claims 26-29 and 37-42 are withdrawn from further consideration as drawn to non-elected subject matter. Claims 30 and 33-36 are objected to allegedly because the claims encompass non-elected inventions and/or species. Claims 30-36 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The specification is objected to for certain alleged informalities.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The Examiner has objected to the specification because in the Brief Description of the Drawings, references to Figure 10(a) and Figure 10(b) at page 21, lines 4 and 7 of the specification, are incorrect. In addition, the Examiner points out that on pages 40-41 (Table 2) of the specification, the superscript at the end of each sequence is barely visible.

Applicants have amended the specification at page 21 to refer to Figure 9A and Figure 9B, respectively. Applicants have also amended the specification at page 41 (Table 2) to add a notation to clarify that the superscript number at the end of each sequence represents the corresponding sequence identifier. As such, Applicants respectfully submit that the objection to the specification is overcome. Withdrawal of the objection is therefore respectfully requested.

With respect to the claims, the Examiner has made the restriction requirement final. Accordingly, claims 26-29 and 37-42 are withdrawn from further consideration as drawn to non-elected subject matter. Claims 30-36 are under consideration.

In response, Applicants have canceled claims 26-29 and 37-42 without prejudice by way of the instant amendment. Applicants reserve the right to pursue the non-elected subject matter in a divisional application.

The Examiner has objected to claims 30 and 33-36, allegedly because the claims encompass non-elected inventions and/or species. The Examiner appears to be referring to the recitation of cytokines other than the elected cytokine species, oncostatin M.

Applicants respectfully submit that the claims will be restricted to the elected species only when no generic claim is finally held to be allowable. At this point, the Examiner has not identified any prior art that would render the generic claims (claims 30-31) unpatentable. The only non-final rejection of the generic claims is raised under 35 U.S.C. §112, first paragraph. As it is believed that the generic claims are fully enabled, as set forth below, it is respectfully submitted that Applicants are entitled to consideration of species in addition to the elected species of oncostatin M. Accordingly, withdrawal of the objection to claims 30 and 33-36 is respectfully requested.

Claims 30-36 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Claims 30-36 are drawn to a method of inhibiting the proliferation of malignant breast cancer cells in a mammal by administering a selected cytokine, e.g., oncostatin M (OSM).

It is observed that the specification provides exemplification of the inhibitory effects of OSM on the proliferation of malignant breast cancer cells *in vitro*. The Examiner argues that the specification does not provide any guidance or exemplification of any correlation between inhibiting proliferation of a breast cancer cell line in the presence of OSM *in vitro* and administering OSM to a mammal to inhibit the proliferation of malignant breast cancer cells *in vivo*. The Examiner has also cited a number of references which discuss various obstacles in cancer therapy. The Examiner concludes that one skilled in the art would be forced into undue experimentation to practice the claimed invention.

Applicants respectfully submit that the present application recognizes for the first time that cytokines, such as oncostatin M (OSM), interleukin-6 (IL-6), interleukin-11 (IL-11), leukemia inhibitory factor (LIF) and epidermal growth factor (EGF), have inhibitory effects on the proliferation of malignant breast cancer cells. The specification provides a thorough characterization of the inhibitory effects of OSM on the proliferation of malignant breast cancer

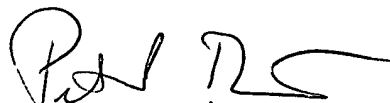
cells *in vitro*, including the inhibitory doses, and the effects on cell cycle, cell morphology and the expression of various cell surface receptors. See pages 31-38 of the specification, for example. In addition, the specification provides exemplification of the inhibitory effects on the proliferation of malignant breast cancer cells *in vitro* of other cytokines, including EGF (e.g., at pages 32 and 34), IL-6 (e.g., pages 36-37), LIF (e.g., pages 36-37) and IL-11 (e.g., pages 36-37).

It is respectfully submitted that those skilled in the art would consider that the *in vitro* characterizations provided in the specification are reasonably correlated to inhibitory effects of the selected cytokines on the proliferation of malignant breast cancer cells *in vivo*. Applicants do not dispute that obstacles may exist, or that additional experimentation may be required to optimize the parameters for *in vivo* administration of a selected cytokine. However, there is no evidence that the obstacles are not insurmountable. Moreover, some experimentation is permissible. In re Wands, 858 F.2d 731, 736-737, 8 U.S.P.Q. 1400, 1404 (Fed Cir. 1988). Necessary experimentation is not determinative of the question of enablement; only undue experimentation is fatal under the provisions of 35 U.S.C. §112, first paragraph. Id. Applicants respectfully submit that the specification has provided sufficient guidance to those skilled in the art to practice the claimed methods without undue experimentation.

Therefore, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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